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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,937	02/15/2002	Herbert M. Dean	dean0202con	3941

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/076,937	Applicant(s) DEAN ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a continuation of US application Serial No. 09/717,987.

Applicant's election with traverse of the invention of Group I, claims 1-10 in Paper No. 3, received June 3, 2002 is acknowledged. The traversal is on the ground(s) that the example listed by the examiner: calcium channel blocker and aspirin, is not the same as the composition used to practice the instant method. In addition, calcium channel blockers and beta-adrenergic blockers are different and distinct pharmaceutical compounds. This is not found persuasive because this is precisely the reason that the instant method and the composition are different and distinct. As discussed in the office action mailed April 23, 2002, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating cardiovascular disease can be practiced with another materially different product such as calcium channel blocker. Since the method can be practiced with a materially different product, the inventions are separate and distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 3, received June 3, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearle (American Heart Journal, 1990 Sep; 120(3):739-742), Carruthers et al. (American Journal of Cardiology, 1993;71:575-581), Abby et al. (Journal of the American Board of Family Practice, 1998; 11(5):391-398), Oakley et al. (The Journal of Nutrition, 1996;126(3): 751S – 755S), and Behounek et al. (US Patent 5,691,375) in view of Rork et al. (US Patent 5,882,682).

Pearle teaches that beta-blockers such as timolol, metoprolol, atenolol, and propranolol reducing the overall mortality and the incidence of recurrent myocardial infarction (See the abstract; also page 740, col. 1, second paragraph).

Carruthers et al. teaches atenolol reducing the risk of coronary heart disease (See the abstract).

Abby et al. teaches folic acid and vitamin B_6 are useful in reducing the risk of coronary heart disease such nonfatal myocardial infarction and fatal coronary heart disease (See particularly page 395, Table 2).

Oakley et al. teaches vitamin B_{12} supplement is useful with folic acid administration to avoid the folic acid adverse effect: B_{12} deficiency (See page 3, third and fourth paragraph).

Behounek et al. teaches HMG-CoA reductase inhibitor such as pravastatin is useful in reduce the risk of cardiovascular event (See the abstract).

The references do not expressly the incorporation of beta-blockers such as timolol, metoprolol, atenolol, and propranolol, HMG-CoA reductase inhibitors such as pravastatin, folic acid, vitamin B_6, and vitamin B_{12} into a single once-a-day dosage unit.

Rork et al. teaches a sustained release system that can include beta-bloackers such as timolol, metoprolol, atenolol, and propranolol and statin cholesterol lowering agents such as simvastatin, pravastatin, and lovastatin (See col. 6, line 64-66 and col. 7, line 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate beta-blockers such as timolol, metoprolol, atenolol, and propranolol, HMG-CoA reductase inhibitors such as pravastatin, folic acid, vitamin B_6, and vitamin B_{12} into a single once-a-day dosage unit.

One of ordinary skill in the art would have been motivated to incorporate beta-blockers, such as timolol, metoprolol, atenolol, and propranolol, HMG-CoA reductase inhibitors, such as pravastatin, folic acid, vitamin B_6, and vitamin B_{12} into a single once-a-day dosage unit. All the agents herein: different beta-blockers such as timolol, metoprolol, atenolol, and propranolol, HMG-CoA reductase inhibitors such as pravastatin, folic acid, and vitamin B_6 are all known to reduce risk of cardiovascular diseases. Possessing the teachings of the cited prior art, combining two or more agents which are known to be useful to reduce risk of cardiovascular disease individually into a single sustained release, once-daily composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, possessing the teaching of Oakley et al., one of ordinary skill in the art would incorporate vitamin B_{12} into any folic acid containing composition including the instant composition since vitamin B_{12} administration would prevent folic acid adverse effect such as vitamin B_{12} deficiency.

Response to Arguments

Applicant's arguments filed June 3, 2002 averring applicant's intended use of the instant composition have been fully considered but they are not persuasive. Firstly, Applicant's argument is directed to how to enhance compliance, simplify treatment, increase convenience, and reduce cost. Those arguments are all directed to intended use of the instant composition not recited in the claims. Please note that any arguments directed to unclaimed limitations are considered moot. Secondly, the recitation of the intended use does not lend any patentable weight to composition claims. Please note

that the court sitting *in banc* ruled that the recitation of new utility of old and well-known composition does not render that composition new (See *In re Dillon* 16 USPQ 2d, 1897 at 1900 (CAFC 1990)). To illustrate the point, please consider the following example: a composition containing 325 mg aspirin for treating headache and another composition containing 325mg of aspirin for reducing the risk of myocardial infarction are the same composition because both composition contains exactly the same amount of the same active: 325mg of aspirin, regardless of what two compositions intended uses might be. In the instant case, possessing the teachings of the cited prior art, one of ordinary skill in the art would reasonable expect all the ingredients to be incorporated into a single composition since all the actives herein are known to be useful for reducing risk of cardiovascular diseases. In other words, the enhanced patient compliance, simplified treatment, increased convenience, and reduced cost by utilizing the composition do not alter the make-up, i.e., the essential components, of the composition. Therefore, these factors are not relevant to patentability.

Applicant's argument filed June 3, 2002 averring that beta-blockers and HMG-CoA reductase inhibitors are not used for the very same purpose have been considered but are considered moot in view of the new ground of rejection set forth in the instant office action.

Response to Dr. Dean's Declaration

Dr. Dean's remarks regarding the cardiovascular preventive therapeutic aspect of the instant claimed composition with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection. Please see the discussion above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

San-ming Hui
July 29, 2002